REMARKS

Upon entry of this amendment, claims 23, 28, 48-53, 55, 59-62, and 64-68 are pending. Claim 64 has been amended to correct a typographical error. New claim 68 has been added. Support for this amendment can be found at least at page 17, lines 10-14 of the specification as-filed. Applicants have amended the specification to include the priority references. No new matter has been added.

Applicants draw the Examiner's attention to the co-ownership of the instant application between Genetics Institute, LLC and The Johns Hopkins University. Each of US 5,710,023, US 6,248,714, US 6,268,480, and US 6,214,559 are assigned to Genetics Institute, LLC. The rejections of the claims are addressed in detail below.

Priority

According to the Examiner, because it is unclear which application receives the appropriate priority, 12/13/99 is the effective filing date used for the purpose of applying prior art. (*See* Advisory Action at page 2.) Applicants note that the specification has been amended to specify that this application is a national application of PCT/US99/29493, filed December 13, 1999, which is a continuation-in-part of USSN 09/211,335, filed December 14, 1998. Thus, this application claims priority to December 14, 1998. A request for a corrected filing receipt to note this priority information is enclosed with this response.

Obviousness-Type Double Patenting

Claims 23, 28, 48, 55, 59 and 64 are rejected as unpatentable over claims 1, 6-8 and 14 of Collins *et al.*, US Patent No. 6,248,714 ("the '714 patent") in view of Cookson *et al.*, US Patent No. 6,387,615 ("the '615 patent"), Hamelmann *et al.* (Allergy and Clinical Immunology

International, Abstract, Vol. 10/2:59-63, 1998; "Hamelmann"), and King *et al.*, (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999; "King"). The rejection is traversed.

First, the rejection cannot be sustained because King is not prior art to the claimed subject matter. Applicants have amended the specification to specify that this application claims priority to 09/211,335, which was filed December 14, 1998. King was made available to the public in August of 1999. As King was published after the priority date of the instant application, this reference does not qualify as prior art.

Moreover, in an obviousness-type double-patenting analysis, the claim or claims in the earlier patent and the claim or claims in the later patent application are compared, and their differences determined. See, e.g., Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1326, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999). The next step in the analysis involves determining whether the differences in subject matter between the two claims render the claims patentably distinct. Id. at 1327, 52 USPQ2d at 1595. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

Claims 1-15 of the '714 patent include 2 independent claims:

> 1. A method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject, said method comprising administering a therapeutically effective amount of a pharmaceutical composition comprising a protein and a pharmaceutically acceptable carrier, wherein said protein comprises an amino acid sequence selected from the group consisting of:
> (a) the amino acid sequence of SEQ ID NO:2;
> (b) the amino acid sequence of SEQ ID NO:2 from amino acids 22 to 334;
> (c) the amino acid sequence of SEQ ID NO:2 from amino acids 357 to 383;
> (d) the amino acid sequence of SEQ ID NO:4;
> (e) the amino acid sequence of SEQ ID NO:4 from amino acids 26 to 341; and
> (f) the amino acid sequence of SEQ ID NO:4 from amino acids 363 to 380.

> 6. A method of treating an Ig-mediated condition in a mammalian subject, said method comprising administering a therapeutically effective amount of a pharmaceutical composition comprising a proterin and a pharmaceutically acceptable carrier, wherein said protein comprises an amino acid sequence selected from the group consisting of:
> (a) the amino acid sequence of SEQ ID NO:2;
> (b) the amino acid sequence of SEQ ID NO:2 from amino acids 22 to 334;
> (c) the amino acid sequence of SEQ ID NO:2 from amino acids 357 to 383;
> (d) the amino acid sequence of SEQ ID NO:4;
> (e) the amino acid sequence of SEQ ID NO:4 from amino acids 26 to 341;
> (f) the amino acid sequence of SEQ ID NO:4 from amino acids 363 to 380; and
> (g) fragments of (a)-(f) having the ability to bind IL-13 or a biologically active fragment thereof.

Applicants' claim 23, from which claims 48-53, and 55, depend, requires inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject having an allergen-induced airway hyper responsiveness. Similarly, claim 28, from which claims 59-62, and 64-67 depend, requires a method of treating an allergen-induced airway hyper responsiveness in a mammalian subject.

The claims of the '714 patent do not disclose inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject having an allergen-induced airway hyper responsiveness. Neither do the claims of the '714 patent disclose a method of treating an allergen-induced airway hyper responsiveness in a mammalian subject. Therefore, the pending claims subject to the rejection are distinct from the claims of the '714 patent on at least this basis. Moreover, this distinction is a patentable distinction because there is no suggestion of an allergen-induced airway hyper responsiveness in the claims of the '714 patent. In view of the foregoing comments, reconsideration and withdrawal of the rejection for obviousness-type double patenting is requested.

Rejections under 35 USC § 103(a)

Claims 23, 28, 48-53, 55, 59-62, and 64-67 are rejected as unpatentable over Collins *et al.*, US Patent No. 5,710,023 ("the '023 patent") in view of Hamelmann, and King. As discussed above, King is not prior art to the claimed invention.

The rejection under 35 USC § 103(a) cannot be sustained with the remaining references. Claims 23 and 28, from which the other rejected claims depend, are directed to the treatment of an allergen-induced airway hyper responsiveness (AHR), which is neither mentioned nor suggested in the '023 patent. Hamelmann fails to disclose that the inhibition of IL-13 binding to IL-13R is useful in any setting and therefore does not cure the deficiencies of the '023 patent. Moreover, Applicants submit that Hamelmann teaches away from the present invention. Specifically, Hamelmann discloses that the role of cytokines in AHR is "...not well defined and requires further delineation." (Hamelmann at page 59, right column.) Hamelmann concludes that IL-5 is a key factor in the development of airway inflammation and AHR, and suggests that anti-IL-5 therapy would be beneficial in the treatment of AHR. (*See* Hamelmann at page 63, left column.) Hamelmann does not disclose or suggest that the inhibition of IL-13 binding to IL-13R could be useful in the treatment of AHR. Thus, Applicants submit that the rejected claims are not obvious in view of the '023 patent and Hamelmann, either alone or in combination. This rejection should be withdrawn.

Claims 23, 28, 48-53, 55, 59-62, and 64-67 are rejected as unpatentable over the '714 patent in view of Hamelmann and King. As King was published after the priority date of the instant application, this reference does not qualify as prior art.

The rejection under 35 USC § 103(a) cannot be sustained with the remaining references. Claims 23 and 28, from which the other rejected claims depend, are directed to the treatment of

an allergen-induced airway hyper responsiveness (AHR), which is neither mentioned nor suggested in the '714 patent. Hamelmann fails to disclose that the inhibition of IL-13 binding to IL-13R is useful in any setting and therefore does not cure the deficiencies of the '714 patent. Rather, as stated above, Hamelmann teaches away from the present invention, and suggests that anti-IL-5 therapy would be beneficial in the treatment of AHR. (*See* Hamelmann at page 63, left column.) Hamelmann does not disclose or suggest that the inhibition of IL-13 binding to IL-13R could be useful in the treatment of AHR. Thus, Applicants submit that the rejected claims are not obvious in view of the '714 patent and Hamelmann, either alone or in combination. This rejection should be withdrawn.

Claims 23, 28, 48-53, 55, 59-62, and 64-67 are rejected under 35 USC § 103(a) as being obvious over Collins *et al.*, US Patent No. 6,268,480 ("the '480 patent"), in view of Hamelmann and King. King does not qualify as prior art for the reasons discussed above.

The rejection under 35 USC § 103(a) cannot be sustained with the remaining references. Claims 23 and 28, from which the other rejected claims depend, are directed to the treatment of an allergen-induced airway hyper responsiveness, which is neither mentioned nor suggested in the '480 patent. Hamelmann fails to disclose that the inhibition of IL-13 binding to IL-13R is useful in any setting and therefore does not cure the deficiencies of the '480 patent. Moreover, as discussed above, Hamelmann teaches away from the present invention.

Thus, Applicants submit that the rejected claims would not be obvious in view of the '480 patent and Hamelmann, either alone or in combination. This rejection should be withdrawn.

Claims 23, 28, 48-53, 55, 59-62, and 64-67 are rejected under 35 USC § 103(a) as being obvious over Collins *et al.* US Patent No. 6,214,559 ("the '559 patent") in view of Hamelmann

and King. King does not qualify as prior art for the reasons discussed above. The rejection under 35 USC § 103(a) cannot be sustained with the remaining references.

Claims 23 and 28, from which the other rejected claims depend, are directed to the treatment of an allergen-induced airway hyper responsiveness, which is neither mentioned nor suggested in the '559 patent. Hamelmann fails to disclose that the inhibition of IL-13 binding to IL-13R is useful in any setting and therefore does not cure the deficiencies of the '559 patent. Moreover, as discussed above, Hamelmann teaches away from the present invention, and suggests that anti-IL-5 therapy would be beneficial in the treatment of AHR.

Thus, Applicants submit that the rejected claims would not be obvious in view of the '559 patent and Hamelmann, either alone or in combination. This rejection should be withdrawn.

Applicants submit that the application is in condition for allowance, and such action is respectfully requested. Please charge any payments or credit any overpayments of the same to Deposit Account No. 50-0311, reference 22058-514 NATL.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529
David E. Johnson, Reg. No. 41,874
Attorneys for Applicants
c/o MINTZ LEVIN
Tel.: (617) 542-6000
Fax: (617) 542-2241
Customer No. 30623

Dated: October 29, 2007